

Exhibit P



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

The General Counsel
Washington, D.C. 20201

**ADVISORY OPINION ON THE PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT AND
THE MARCH 10, 2020 DECLARATION UNDER THE ACT
APRIL 17, 2020, AS MODIFIED ON MAY 19, 2020**

Purpose of this Advisory Opinion

On March 10, 2020, the Secretary of Health and Human Services (Secretary) issued a Declaration under the Public Readiness and Emergency Preparedness Act (PREP Act), effective February 4, 2020, for certain medical products to be used against COVID-19. *See* 85 Fed. Reg. 15,198, 15,202 (March 17, 2020); *see also* Pub. L. No. 109-148, Public Health Service Act § 319F-3, 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e.

We have received requests for advisory opinions, especially from those donating goods and services, on whether various activities qualify for PREP Act immunity. The Office of the General Counsel will make every effort to respond to each request. But we have limited resources, especially in this time of national emergency. To minimize the need to request an advisory opinion, we issue this omnibus advisory opinion that should address most questions and concerns about the scope of PREP Act immunity during the Coronavirus disease 2019 (COVID-19) pandemic.

This advisory opinion sets forth the current views of the Office of the General Counsel.¹ It is not a final agency action or a final order. Nor does it bind HHS or the federal courts. It does not have the force or effect of law.

The PREP Act

PREP Act immunity applies to any “covered person” with respect to all “claims for loss” caused by, arising out of, relating to, or resulting from the “administration” or the “use” of a “covered countermeasure” if a declaration has been issued with respect to that countermeasure. 42 U.S.C. § 247d-6d(a)(1). We often receive questions about whether a medical product is a covered countermeasure, whether a person is a covered person, and whether a specific activity qualifies as use or administration of a covered countermeasure.

Therefore, this advisory opinion

- provides a list of covered countermeasures subject to an Emergency Use Authorization (EUA);²

¹ *See Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 647-48 (6th Cir. 2004) (holding that the Chief Counsel of the National Highway Traffic Safety Administration had delegated authority to issue advisory opinions to regulated entities in fulfillment of a congressional directive to promote regulatory compliance); 5 U.S.C. § 301 (“The head of an executive department ... may prescribe regulations for the government of his department, the conduct of its employees, [and] the distribution and performance of its business[.]”).

² *See* Appendix A, <https://www.fda.gov/media/136702/download> Appendix B, <https://www.fda.gov/media/136832/download>.

- advises that an entity or individual who complies with all other requirements of the PREP Act and the conditions of the Secretary's declaration will not lose PREP Act immunity—even if the medical product at issue is *not* a covered countermeasure—if that entity or individual reasonably could have believed that the product was a covered countermeasure;
- advises that a person who complies with all other requirements of the PREP Act and the conditions of the Secretary's declaration will not lose PREP Act immunity—even if the person at issue is *not* a covered person—if the entity or individual reasonably could have believed that the person was a covered person; and
- sets forth HHS's view that covered persons should take, and document, reasonable precautions under the current emergent circumstances to facilitate the safe use or administration of covered countermeasures and to make those documents publicly and easily available.

If all requirements of the PREP Act and the declaration are met, immunity covers claims for loss sounding in tort or contract, as well as claims for loss relating to compliance with local,³ state, or federal laws, regulations, or other legal requirements. Immunity applies when a covered person engages in activities related to an agreement or arrangement with the federal government, or when a covered person acts according to an Authority Having Jurisdiction to respond to a declared emergency. We interpret these two conditions broadly to include (1) any arrangement with the federal government, or (2) any activity that is part of an authorized emergency response at the federal, regional, state, or local level. Such activities can be authorized through, among other things, guidance, requests for assistance, agreements, or other arrangements. Because the Secretary issued a Public Health Emergency declaration on January 31, 2020, effective as of January 27, 2020, the immunity granted by the PREP Act under this declaration applies regardless of whether state or local authorities have declared states of emergencies.

A few caveats about PREP Act immunity: *First*, PREP Act immunity is not absolute. For example, the PREP Act does not provide immunity against federal enforcement actions brought by the federal government—whether civil, criminal, or administrative. Nor does the PREP Act provide immunity against suit and liability for claims under federal law for equitable relief. PREP Act immunity (exempting preemption) is also limited to claims for personal injury or damage to property. *Second*, the PREP Act replaces certain damages claims that would normally be brought in court with a no-fault compensation system outlined at 42 C.F.R. pt. 110. *Third*, PREP Act immunity must be read in light of the PREP Act's broad, express-preemption provision.⁴

³ While PREP Act immunity does not expressly extend to local laws, the Act expressly preempts any State and local law that “is different from, or is in conflict with, any requirement applicable under [the PREP Act].” 42 U.S.C. § 247d-6d(b)(8).

⁴ Under § 247d-6d(b)(8)(A), (1) “no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that is different from, *or is in conflict with*, any requirement applicable under this section”

Covered Countermeasures

The PREP Act authorizes the Secretary to issue a declaration to provide liability immunity to certain individuals and entities (covered persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (covered countermeasures). Under the March 10, 2020 declaration, covered countermeasures are any

antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product.

85 Fed. Reg. 15,198, 15,202 (March 17, 2020).

Any drug, device, or biological product that is approved, cleared, or licensed by the FDA and is used to diagnose, mitigate, prevent, treat, cure, or limit the harm of COVID-19 is a covered countermeasure. The Coronavirus Aid, Relief, and Economic Security (CARES) Act § 3103, Pub. L. No. 116-136 (March 27, 2020), amended the PREP Act to add respiratory protective devices to the list of covered countermeasures so long as they are NIOSH approved and determined by the Secretary to be a priority for use during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act.⁵ *See* 42 U.S.C. § § 247d, 247d-6d(i)(1)(D). Any drug, device, or biological product authorized for emergency use with respect to COVID-19 under an EUA, described in Emergency Use Instructions (EUI) issued by the CDC, or being researched under certain investigational provisions (*i.e.*, IND, IDE) to treat COVID-19 is a covered countermeasure. *See* 21 C.F.R. pts. 312 and 812. In addition, as noted above, the CARES Act amended the PREP Act to include certain respiratory protective devices. These requirements apply equally to products held in the public and private sectors.

Covered countermeasures include, among other things, a “qualified pandemic or epidemic product.” *See* 42 U.S.C. § 247d-6d(i)(1)(A). The term “qualified pandemic or epidemic product” means

a drug ... biological product ... or device [as] defined ... [in] the Federal Food, Drug, and Cosmetic Act ... that is

(A) (i) a product manufactured, used, designed, developed, modified, licensed, or procured— (I) to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or (II) to limit the harm such pandemic or epidemic might otherwise cause;

and (2) relates to, among other things, use or administration of the covered countermeasure. (Emphasis added).

⁵ The Secretary issued an amendment to the Declaration effective March 27, 2020 to address this statutory change. 85 Fed. Reg. 21,012 (April 15, 2020).

- (ii) a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in clause (i); or
- (iii) a product or technology intended to enhance the use or effect of a drug, biological product, or device described in clause (i) or (ii); and

- (B) (i) approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 351 *et seq.*] or licensed under section 262 of this title;
- (ii) the object of research for possible use as described by subparagraph (A) and is the subject of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. §§ 355(i), 360j(g)]; or
- (iii) authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. §§ 360bbb–3, 360bbb–3a, 360bbb–3b].

42 U.S.C. § 247d-6d(i)(7).

Thus, in order to meet the definition of a qualified pandemic or epidemic product, a product

- (1) must be used for COVID-19; and
- (2) must be
 - (a) approved, licensed, or cleared by FDA;
 - (b) authorized under an EUA;
 - (c) described in an EUI; or
 - (d) used under either an Investigational New Drug (IND) application or an Investigational Device Exemption (IDE).⁶

The number of products used for COVID-19 that are approved, licensed, or cleared are too numerous to list. But we have found that industry has often sought clarity regarding whether certain products, including diagnostic tests and personal protective equipment (PPE), are covered by EUAs. Footnote 2, above, links to a list those products that are covered by EUAs. We hope that this list proves helpful. HHS will use its best efforts to regularly update that list, although there may be a lag between the actual issuance of the EUA by FDA and the product's appearance on the list.

Given the broad scope of PREP Act immunity, Congress did not intend to impose a strict-liability standard on covered persons for determining whether a product is a covered countermeasure. Instead, we believe that a person or entity that otherwise meets the requirements for PREP Act immunity will not lose that immunity—even if the product is *not* a covered countermeasure—if that person or entity reasonably could have believed that the product was a covered countermeasure. *See, e.g.*, 42 U.S.C. § 247d-6d(a)(4)(B) (applying the “reasonably-could-have-believed” standard to predicate

⁶ While certain information about products under an IND or IDE is confidential commercial information and not subject to disclosure, some information is available to the public on clinicaltrials.gov.

requirements for PREP Act immunity not involving the actual use and administration of covered countermeasures).

For example, FDA has issued EUAs for certain COVID-19 tests and PPE. A covered person purchases 500,000 tests or respirators that appear to be authorized under an EUA. The covered person has taken reasonable steps—under the current, emergent circumstances—to substantiate the authenticity of the products. But it turns out that some or all of the products are counterfeit. Under those circumstances, we believe that the person would be immune against a claim arising out of the use of a counterfeit test or respirator.

Covered Person

The PREP Act provides immunity to a “covered person” for certain activities (*e.g.*, manufacturing, distributing, using, or administering) involving a “covered countermeasure,” as defined in the PREP Act and delineated in a PREP Act declaration issued by the Secretary. The term “covered person,”

when used with respect to the administration or use of a covered countermeasure, means—

(A) the United States; or

(B) a person or entity that is—

- (i) a manufacturer of such countermeasure;
- (ii) a distributor of such countermeasure;
- (iii) a program planner of such countermeasure;
- (iv) a qualified person who prescribed, administered, or dispensed such countermeasure; or
- (v) an official, agent, or employee of a person or entity described in clause (i), (ii), (iii), or (iv).

42 U.S.C. § 247d-6d(i)(2). We have received questions about the meaning of “program planner” and “qualified person.”

The term “program planner” means

a State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with [the Secretary’s declaration].

42 U.S.C. § 247d-6d(i)(6).

Under the Secretary's declaration, "[A] private sector employer or community group or other 'person' can be a program planner when it carries out the described activities." 85 Fed. Reg. at 15,202.

The term "qualified person," when used

with respect to the administration or use of a covered countermeasure, means— (A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or (B) a person within a category of persons so identified in a declaration by the Secretary.

42 U.S.C. § 247d-6d(i)(8).

With respect to that second category, the Secretary, through Section V of his declaration, has determined that qualified persons also include

[a]ny person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in Section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a Declaration of an emergency[.]

85 Fed. Reg. at 15,202.

Therefore, an Authority Having Jurisdiction has broad powers to extend PREP Act immunity to additional individuals as part of a public health and medical emergency response. The Authority Having Jurisdiction does so by authorizing "any person" to "prescribe, administer, deliver, distribute or dispense the Covered Countermeasures." Section VII of the declaration explains that "[t]he Authority Having Jurisdiction means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (e.g., city, county, tribal, state, or federal boundary lines) or functional (e.g., law enforcement, public health) range or sphere of authority." *Id.* As the lead federal public-health agency that has legal responsibility and authority for responding to the COVID-19 emergency, HHS is an Authority Having Jurisdiction, but it is not the only Authority Having Jurisdiction to respond to the COVID-19 emergency.

The following is an example of a qualified person under Sections V and VII of the declaration. In response to the COVID-19 emergency, the HHS Office of the Assistant Secretary for Health (OASH) issued guidance for licensed pharmacists to order and administer COVID-19 tests, including serology tests, that the FDA has authorized. Such tests are covered countermeasures under the declaration. Thus, under Sections V and VII of the declaration, such pharmacists are covered persons. Specifically, they are qualified persons, as they are acting in accordance with guidance from HHS—an Authority Having Jurisdiction to respond—following a declared emergency by the Secretary. The pharmacists are covered as qualified persons (and hence as covered persons) even if they may not be

licensed or authorized by the State to prescribe the tests pursuant to § 247d-6d(i)(8)(A)), because they fit within the alternative definition of “qualified persons” pursuant to paragraph § 247d-6d(i)(8)(B), as provided by the Secretary in the declaration.

As with covered countermeasures, an entity or person that otherwise meets the requirements for PREP Act immunity will not lose that immunity—even if the entity or person is *not* a covered person—if that entity or person reasonably could have believed, under the current, emergent circumstances, that the person was a covered person. *See, e.g.*, 42 U.S.C. § 247d-6d(a)(4)(B).

For example, a pharmacy allows its licensed pharmacists to order FDA-authorized, self-swab COVID-19 tests pursuant to the OASH guidance. Notwithstanding the pharmacy’s reasonable-compliance measures to ensure current licensure, it turns out that one of the pharmacists had inadvertently allowed his license to expire. Under those circumstances, the pharmacy would still be immune against a lawsuit relating to the COVID-19 test prescribed by that pharmacist.

Reasonable Precautions

Under the PREP Act, immunity is broad. As a general matter, a covered person is immune from liability for all claims for loss except for willful misconduct that proximately caused death or serious injury. 42 U.S.C. § 247d-6d(c)(3). Suits alleging an exception to immunity for covered persons can only be brought before a three-judge court in the United States District Court for the District of Columbia. 42 U.S.C. § 247d-6d(e)(1), (5). And to prevail, a plaintiff must establish, by clear and convincing evidence, that the willful misconduct proximately caused death or serious injury. 42 U.S.C. § 247d-6d(c)(3).

But even then, certain acts or omissions remain immune from suit. For example, under 42 U.S.C. § 247d-6d(c)(4),

Notwithstanding any other provision of law, a program planner or qualified person shall not have engaged in “willful misconduct” as a matter of law where such program planner or qualified person acted consistent with applicable directions, guidelines, or recommendations by the Secretary regarding the administration or use of a covered countermeasure that is specified in the declaration under subsection (b), provided either the Secretary, or a State or local health authority, was provided with notice of information regarding serious physical injury or death from the administration or use of a covered countermeasure that is material to the plaintiff’s alleged loss within 7 days of the actual discovery of such information by such program planner or qualified person.

And under 42 U.S.C. § 247d-6d(c)(5), certain acts or omissions by a manufacturer or distributor and “subject to regulation by this chapter or by the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 *et seq.*]” will not constitute willful misconduct if (1) “neither the Secretary nor the Attorney General has initiated an enforcement action with respect to such act or omission” or (2) “such an enforcement action has been initiated and the action has been terminated or finally resolved without a covered remedy.”

Nevertheless, HHS encourages all covered persons using or administering covered countermeasures to document the reasonable precautions they have taken to safely use the covered countermeasures.

For example, consider a distributor of medical products that sources PPE from a new supplier abroad in a good-faith attempt to quickly deliver PPE to American communities affected by COVID-19. Among other things, that distributor assesses the supplier's facility to confirm that the supplier actually manufactures the PPE. The distributor also confirms that the supplier has quality-control processes in place.

Under those circumstances, the distributor may wish to make available to the purchaser information about the reasonable efforts that the distributor had taken to safely use the covered countermeasures. Purchasers such as hospitals would then be able to make more informed decisions about how best to use the PPE. Overall, this would provide greater transparency in implementing the PREP Act.

Compensation for Injuries

The PREP Act, like workers' compensation or the National Vaccine Injury Compensation Program, substitutes a no-fault, speedy compensation system in place of expensive and uncertain litigation. Those who have been seriously injured or died as the direct result of a covered countermeasure administered or used under a declaration may seek compensation from the Covered Countermeasures Process Fund. Requests for benefits must be made to the Health Resources and Services Administration's Countermeasures Injury Compensation Program (CICP). Compensation for serious injuries may be available to eligible requesters under CICP.

A serious injury generally means a physical injury that warranted hospitalization (whether or not the person was actually hospitalized) or that led to a significant loss of function or disability. 42 C.F.R. § 110.3(z). CICP pays reasonable and necessary medical benefits. CICP also pays lost wages to eligible recipients. Death benefits may also be available to certain survivors of eligible individuals who died as a direct result of the administration or use of a covered countermeasure. CICP is payer of last resort. So benefits are reduced by the amounts payable by other public and private third-party payers (such as health insurance and workers' compensation). The regulations implementing the CICP are at 42 C.F.R. pt. 110.

Compensation for injuries is more limited than the liability immunity afforded under the PREP Act. As described above, the PREP Act provides immunity for all claims for loss. But CICP will provide compensation only for eligible claims of serious physical injury or death. CICP will not compensate claims related to emotional injury, fear of injury, business losses, or other types of claims for which immunity is provided. Information about this program can be found at <https://www.hrsa.gov/cicp/about/index.html> or by calling 855-266-2427.

Limitations

This Advisory Opinion may be supplemented or modified. It is intended to minimize the need for individual advisory opinions.

Persons seeking PREP Act immunity are responsible for determining whether their products are covered countermeasures, whether a person or entity is a covered person, whether reasonable precautions have been taken to facilitate the safe use of covered countermeasures, and in general, whether immunity applies to them and their activities.

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May 19, 2020